22

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA; THE STATES OF CALIFORNIA, DELAWARE FLORIDA, HAWAII, ILLINOIS, MASSACUSSETTS, NEVADA, NEW MEXICO, NEW YORK, TENNESSEE, TEXAS, VIRGINIA AND THE DISTRICT OF COLUMBIA ex rel. [UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendant.	Civil Action No. 04-4401 SECOND AMENDED COMPLAINT

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. §§3729 et. seq.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA; THE STATES OF CALIFORNIA, DELAWARE FLORIDA, HAWAII, ILLINOIS, MASSACUSSETTS, NEVADA, NEW MEXICO, NEW YORK, TENNESSEE, TEXAS, VIRGINIA; AND THE DISTRICT OF COLUMBIA EX REL. BRUCE BOISE, Plaintiffs, v. CEPHALON, INC., Defendant.	Civil Action No. 04-4401 SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. §1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 et seq.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 et seq.]; ILLINOIS WHISTLE BLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. §175 et seq.]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 §5 et seq]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS [N.M. Stat. Ann. §27-2F-1 et seq.]; NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. §§ 187 et. seq.]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. §36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann §8.01-216.1 et seq.]; and DISTRICT OF COLUMBIA PRO-CUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §1-1188.13 et seq.]

FILED UNDER SEAL

JURY TRIAL DEMANDED

Qui tam plaintiff/relator Bruce Boise, through his attorneys Phillips & Cohen LLP and Weinstein Kitchenoff & Asher LLC, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Massachusetts, the State of New Mexico, the State of New York, the State of Nevada, the State of Tennessee, the State of Texas, the State of Virginia and the District of Columbia (collectively "the

States and the District of Columbia"), for his Second Amended Complaint against defendant Cephalon, Inc. alleges based upon personal knowledge, discussions with other former Cephalon employees, and relevant documents, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America, the States of California, Delaware, Florida. Hawaii, Illinois, Massachusetts, Nevada, New Mexico, New York, Tennessee, Texas, Virginia ,and the District of Columbia arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendant Cephalon, Inc. ("Cephalon") and/or its agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et seq., as amended ("the FCA" or "the Act") and its state-law counterparts: the California False Claims Act, Cal. Govt Code §12650 et seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann.§ 27-2F-1 et seq.; the New York False Claims Act, N.Y. State Fin. §§ 187 et. seq., the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 et seq.

2. Since at least 2000, it has been Cephalon's practice to systematically and illegally promote its prescription drugs Gabitril, Provigil, and Actiq for off-label indications. In addition to and in support of its off-label marketing efforts, Cephalon's sales force has offered and made unlawful financial inducements to providers to encourage them to prescribe Cephalon drugs, and/or to switch from competitor products. As alleged below, Cephalon disguises physician inducements as payments for "preceptorships" and speaking fees, among other things.

3. As a direct result of Cephalon's improper practices, federal and state health insurance programs including, but not limited to, Medicaid, MediCal, CHAMPUS/ TRICARE, CHAMPVA and the Federal Employee Health Benefits Program have been caused to pay false or fraudulent claims for reimbursement of off-label uses of the Cephalon prescription drugs that would not have been paid but for the defendant's illegal business practices.

4. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

5. The Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of

up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seeks payment, from the Government that is unwarranted.

6. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

7. Based on these provisions, qui tam plaintiff seeks through this action to recover on behalf of the United States and States that authorize similar qui tam actions, damages and civil penalties arising from Cephalon's making or causing to be made false or fraudulent records, statements and/or claims in connection with its knowing off-label marketing of prescription drugs. Although Cephalon did not directly submit claims for prescription drugs to federal and state health insurance programs, it knew that its illegal off-label marketing practices and illegal inducements would cause the submission of thousands of claims to these health programs for prescriptions that were not eligible for program reimbursement.

II. PARTIES

8. Plaintiff/relator Bruce Boise is a resident of Melbourne Beach, Florida. From 1996 to June, 2003, Mr. Boise was employed by Cephalon in sales representative and sales manager positions in Ohio. Concerned about defendant's misconduct as alleged herein, Boise voluntarily met with FDA officials in January, 2003, and has cooperated thereafter with their efforts to investigate his allegations. He was terminated by the company in 2003 because of his refusal to incorporate improper off-label

marketing strategies into his sales approach and for sharing information regarding Cephalon's misconduct with the FDA.

9. Defendant Cephalon, Inc. ("Cephalon") is an international biopharmaceutical company, incorporated under the laws of the state of Delaware, and headquartered at 145 Brandywine Parkway, West Chester, Pennsylvania, 19380. Its primary business activity in the United States relates to the manufacture and/or sale of the four drugs at issue in this lawsuit: Provigil, Gabitril, and Actiq.

III. JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367 and 31 U.S.C. §3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relator, moreover, would qualify under that section of False Claims Act as an "original source" of the allegations in this Complaint even had such a public disclosure occurred.

11. This Court has personal jurisdiction and venue over the defendant pursuant to 28 U.S.C. §§1391(b) and 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendant has minimum contacts with the United States. Moreover, the defendant can be found in, resides, and transacts business in the Eastern District of Pennsylvania.

12. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the defendant can be found in and transacts business in the Eastern District of Pennsylvania. At all times relevant to this Complaint, defendant regularly conducted substantial business within the Eastern District of Pennsylvania, maintained employees and offices in Pennsylvania and made significant sales within

Pennsylvania. In addition, statutory violations, as alleged herein, occurred in this district.

IV. BACKGROUND

13. The three main prescription drugs manufactured and/or distributed by defendant Cephalon in the United States are Gabitril, Provigil and Actiq. All of these drugs are the subject of this Complaint. For ease of reference, Gabitril, Provigil, and Actiq will be referred to collectively as "the Cephalon prescription drugs" for the remainder of this Complaint.

14. Until 2004, Cephalon pharmaceutical sales and marketing were organized into two therapeutic areas. Gabitril and Provigil sales and marketing efforts are undertaken by Cephalon's Central Nervous System ("CNS") Division. Actiq was marketed by separate sales staff through Cephalon's Pain Division. Beginning in early 2004, Cephalon's sales staffs were combined and expanded to a total marketing staff of approximately 500 sales representatives and managers who now market all the Cephalon prescription drugs together.

15. Cephalon sales representatives and managers receive incentive-based compensation that includes an annual salary, plus a bonus. An individual sales representative's bonus is determined by his/her performance in the relevant market and whether s/he satisfies or surpasses targets for product sales growth. Accordingly, the more prescription drug sold by a Cephalon sales representative or prescribed by providers in his or her territory, the higher his or her compensation will be.

V. APPLICABLE LAW

A. The FDA Regulatory Scheme

16. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

17. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

18. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

19. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the

use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

20. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

21. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

22. An off-label use of a drug can cease to be off label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

23. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to

regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses.

24. With regard to the first practice - disseminating written information - the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

25. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department

of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

26. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

27. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid and other federal health care programs.

1. The Medicaid Program

28. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

29. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered

outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id. §1396r-8(k)(3).

30. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or use of which is supported by one of the drug compendia identified in the Medicaid statute. Id. §1396r-8(k)(6). During the time period relevant to this Complaint, many of the off-label uses of drugs promoted by Cephalon were not eligible for reimbursement from Medicaid because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute. Use of Provigil, for example, for treating fatigue associated with depression, use of Gabitril for fibromyalgia, post traumatic stress disorder, and insomnia, and use of Actiq on an outpatient basis for breakthrough pain other than cancer pain is not supported by the compendia as medically safe and effective, although Cephalon has promoted the drugs for those and other uses in the ways set forth below.

31. Additionally, because Cephalon's unlawful off-label marketing efforts were designed to generate overutilization of their drugs in situations in which the drugs either were not proven safe and effective or were not medically necessary for treatment of patients' specific medical conditions, Cephalon caused physicians to submit claims for reimbursement to Medicaid that were unwarranted and therefor false.

2. Other Federal Health Care Programs

32. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/ TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

33. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, e.g.,TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

34. During the time period relevant to this Complaint, the off-label uses of the Cephalon prescription drugs promoted by Cephalon did not qualify for reimbursement under any of the various federal health care programs because there was inadequate approval or support for such drugs to be eligible for reimbursement and/or because Cephalon's unlawful marketing activity created overutilization of such drugs in situations where they were not medically necessary for treatment of patients' specific medical conditions.

3. The Anti-Kickback Statute

35. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form,

regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

36. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, or other federal health care program.

37. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company to a physician which has as one of its purposes inducement of the physician to write additional prescriptions for the company's pharmaceutical products.

38. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the improper practices cited by the Inspector General are drug companies' payments to physicians where the physician had offered no particular services of benefit to the drug company but the payment appeared to have been based on the volume of business the doctor could generate for the drug company. Id.

39. Compliance with the Anti-Kickback law is a precondition to participation as a health care

provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In Massachusetts and a number of other states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

VI. ALLEGATIONS

40. In the early days of its corporate existence, Cephalon used to take seriously legal restrictions on how it could market pharmaceuticals that it manufactured and/or distributed. Beginning in or about early 2000, however, as its development of the market for on-label use of its products began to mature, the company sought to achieve greater rates of growth and thus began focusing efforts on expanding its sales for off-label uses of its products. The company continued to pay lip service in its written materials to FDA's prohibitions against off-label marketing of prescription drugs, so as to give the false appearance of compliance. However, through oral directives and by altering its marketing program design Cephalon increasingly pressured its sales force to target inappropriate medical specialists and to meet ever-increasing sales quotas that it knew would require its sales force market

off-label uses of its products and to engage in kickbacks and other illegal remunerations in order to reach demanded levels of sales of each of the Cephalon prescription drugs.

A. Cephalon Has Illegally Promoted Provigil for Off-Label Treatments.

41. Until January 2004, Provigil's only on-label indication was for treatment of excessive daytime sleepiness associated with narcolepsy. In January 2004, FDA approved on-label use to include improving daytime wakefulness of patients suffering from obstructive sleep apnea/ hypopnea syndrome and shift work sleep disorder. Since at least January 2000, however, Cephalon was already aggressively marketing Provigil for those conditions, as well as for continued off-label uses such as fatigue associated with depression, fatigue associated with multiple sclerosis, fatigue associated with schizophrenia, chronic fatigue, and for attention deficit hyperactivity disorder in children.

42. To encourage off-label marketing by its sales force, Cephalon de-emphasized sales calls to sleep specialists likely to be treating patients with on-label indications for use of Provigil and directed its sales representatives instead to concentrate their sales calls increasingly to psychiatrists whom Cephalon's research indicated were treating patients likely to suffer the kinds of disorders for which off-label prescriptions could be solicited. Such targeting was done, for example, with psychiatrists who prescribed substantial amounts of anti-depressant drugs, as a means of attempting to develop off-label sales of Provigil for fatigue associated with depression. Cephlan told its sales representatives that they should plan on visiting target physicians 8-10 times per year in order to achieve increased productivity of those physicians in writing new prescriptions for Cephalon drugs.

43. Sales representatives who did not make a priority of calling on psychiatrists identified by Cephalon as likely candidates for off-label sales, were verbally rebuked and/or financially punished for not pursuing those leads.

44. Cephalon also directly manipulated its bonus incentive program to encourage promotion of off-label sales. Prior to 2000, Cephalon had built into its bonus incentive program terms designed to limit incentives for sales personnel unlawfully to market the Cephalon prescription drugs off label. Substantial off-label sales did not count toward fulfillment of sales representatives' sales quotas, and off-label sales were not a basis upon which quarterly bonuses would be earned. In or about 2000, however, when Roy Craig was hired by Cephalon as Vice President of Sales Operations, those constraints were removed. At Craig's direction, required sales quotas were substantially increased, and potential bonuses to be made from increased sales beyond quota levels were uncapped, all in an effort to encourage greater off-label marketing by Cephalon's sales representatives. In fact, required sales quotas came to be raised so high that the only realistic way for sales representatives to reach required (pre-bonus) levels of performance was to find ways to increase off-label sales.

45. During this same period, oral presentations from upper management to sales representatives and managers at Cephalon's national and regional sales meetings became more openly disdainful of FDA's stricture against off-label marketing. Ever-greater attention was directed during conferences to discussing techniques that could be applied by sales representatives when meeting with physicians to turn discussion to potential off-label uses of Cephalon's drugs without being too obvious about what was being done.

46. One technique used to achieve this goal was for sales representatives to bring up the putative mechanism of action (the actual mechanism of action for Provigil is not known, but sales representatives would discuss the suspected mechanism of action as if it were established) of their drugs to physicians orally and with visual aids, shepherd discussion to off-label medical conditions that might be addressed through the same mechanism of action, and ask the physicians if they had patients that might benefit from application of such a therapeutic approach to their conditions.

47. Cephalon-sponsored case studies were touted and made available to physicians by sales representatives in support the claimed off-label benefits. But such studies typically were retrospective analyses solicited by Cephalon from physicians who prescribed Provigil off-label and whose patients the doctors believed the product showed promising effects. Such anecdotal, individual case observations were in lieu of control-group studies designed and executed to measure the efficacy of Cephalon's product compared to placebo treatment or no treatment at all.

48. Strategies also were developed to lure potentially-large off-label prescribers to promotional activities dressed up as continuing medical education ("CME") opportunities. Among these was the recruitment by Cephalon sales representatives in 2001 and 2002 of potentially high-prescribing physicians to attend national training sessions to become speakers for Cephalon's drugs at "Medical Education Programs" that were sponsored locally by the sales representatives). These three-or-four-day speaker training events were done on an all-expense-paid basis at luxury resort locations in Florida, California and Bermuda. Although pitched as presentations by independent experts, in violation of the FDAMA, Cephalon in fact exercises substantial control over the programs. It has hired a psychiatrist, Steven Stahl, to make a presentation which it largely prepared and finally reviewed and

approved and which emphasized potential off-label applications of Cephalon's products. In addition, Cephalon sales representatives sometimes attend the presentations and make themselves available to answer questions about off-label use of Cephalon products that might arise. Indeed, such off-label questions were often "planted" by Cephalon representatives to appear to be unsolicited.

49. Potential "speakers" are chosen to attend speaker training events based on their potential market share as off-label prescribers of Cephalon products. Because they are "trained" as an inducement to write off-label prescriptions, rather than because of any skill as public speakers, many are ill-suited actually to serve as speakers at local events and were never intended to be asked. Those that have been asked to lead local Cephalon "Medical Education Programs" ("MEPs") have been paid speaking fees from the budget of their local Cephalon sales representative to make dinner or lunch presentations to other physicians that Cephalon's sales representatives had identified as potentially significant off-label prescribers of Cephalon drugs. Such payments were made even if no other invited physicians actually attended the planned presentation. However, even good public speakers have been dropped by Cephalon from those that would be hired to lead future Medical Education Programs if experience later showed that they did not themselves write substantial off-label prescriptions for Cephalon's products. In 2003, for example, relator's manager Joe Haygood instructed relator not to hire Dr. Weiss as a speaker at any future MEPs unless and until Dr. Weiss's personal prescription performance substantially improved.

50. Cephalon's local Medical Education Programs are offered as CME opportunities for the local physicians that the sales representatives identified to Cephalon's medical liaisons as promising sales leads to invite. Slide presentations presented at those meetings closely track the presentations

made at the Steven Stahl training sessions, including the high level of attention paid to potential off-label use doctors can make of Cephalon's drugs. As is true with Dr. Stahl's presentation, the local speakers' presentations are also largely prepared (and finally reviewed and approved) by Cephalon's sales representatives, who attend the sessions as well and answer questions regarding off-label use. (Indeed, at one such event in 2003, Phil Tocco, the sales manager for Cephalon's Pittsburgh office, completely supplanted the physician speaker in responding to questions about off-label uses of Cephalon's products. Mark Macrides, another Cephalon sales representative who attended the event, confided to another Cephalon sales manager, Mike Weatherholt, his concern that Tocco's behavior was obviously and completely out of bounds. Weatherholt agreed and raised the concern up the chain of command. In response, Roy Craig called Weatherholt and berated him for being the kind of manager that a sales representative felt comfortable calling to complain about off-labeling marketing practices of other employees.)

51. In 2004 alone, Cephalon planned 430 such medical education dinners for psychiatrists, with an expected attendance of 10-12 doctors per session. In prior years, sales representatives' annual budget for these and other off-label promotional activities has been $20,000-$25,000 each.

52. As physicians have become more reluctant to devote time to such presentations -- because of their growing sense that they are mere marketing ploys -- with the knowledge and implied or explicit consent of their managers, Cephalon's sales representatives have used financial inducements to convince physicians to attend the presentations. Such inducements have included such things as $500 "preceptorship" payments made by the sales representatives to physicians for the putative "educational" purpose of permitting the sales representatives to observe the physician's practice for a

2-4 hour period, so that the sales representative could better understand how the physician evaluates, diagnoses, and treats patients. Such "shadowing," however, in reality has been intended to buy access to physicians, and to reward high-prescribers with financial inducements. Indeed, if physicians were reluctant to have a sales representative present when they are treating patients, sales representatives paid the $500 inducement nonetheless and simply spent the time allotted to the preceptorship in the physician's waiting room or coffee room. (This was an idea proposed by sales representative Rob Rondeau at a Great Lakes Region sales meeting in 2002 or 2003 and approved by Joe Haygood, relator's former manager.) The real purpose of such preceptorship payments has not been educational at all, but to induce physicians to attend a marketing presentation in which one physician hired by Cephalon will discuss off-label use of Cephalon drugs with other physicians Cephalon paid or otherwise convinced to attend.

53. Sales representatives who balked at participating in the off-label marketing of Provigil and other Cephalon drugs through such bogus "Medical Education Programs" were rebuked and financially punished by the company. For instance, Joe Haygood denied relator the bonus he had otherwise earned through his direct sales efforts in 2002 because relator recognized such Medical Education Programs as improper off-label marketing and thus refused to utilize that marketing device as a means of keeping pace with other sales representatives who were willing to do as the company expected.

54. Cephalon further used the off-label marketing information it included in Steven Stahl's presentation to educate its own sales representatives about off-label uses of its products, so that they could effectively promote the drugs off-label to physicians they detailed. After Steven Stahl presented off-label material at Cephalon's national sales meeting in February, 2003, he noted to Mike Thiem, Cephalon's Director of Medical Liaisons, the almost exclusive focus on sales representatives in questions that followed the presentation on the off-label aspects of the presentation. When Thiem thereafter related Stahl's expressed concern about that focus to Roy Craig in relator's presence, Craig's response was that Cephalon hired Stahl and that Cephalon tells Stahl where to draw lines regarding off-label marketing, not the other way around.

55. Cephalon's efforts to transform "educational" and "research" resources into off-label marketing tools extends generally to its use of medical liaisons. Done properly, medical liaisons between a company and the medical community are typically Ph.D.'s who are qualified to coordinate genuine research efforts among academic doctors. Roy Craig has staffed Cephalon's medical liaison instead with former sales representatives, and has used the position primarily as an extension of Cephalon's regional marketing efforts.

56. Consistent with their marketing orientation, Cephalon's medical liaisons frequently sponsor reports on the efficacy of Cephalon products based not double-blind control studies but on retrospective case reviews by physicians who had tried Cephalon's products off-label on their own patients and believed them to have some therapeutic effect. These case review "studies," were then provided to Cephalon's sales representatives so that they could invite other physicians to request the data from Cephalon's "medical liaisons" to support the sales representative's suggested off-label uses

of the drugs.

57. In further violation of the FDAMA, Cephalon also encourages and directs its sales representatives to invite and encourage physicians upon whom they call to request information about off-label usage of Provigil and the other Cephalon prescription drugs from Cephalon as a means of marketing such off-label uses. Sales representatives are provided Medical Information Request Forms ("MIRFs") by Cephalon to offer physicians in order to make such requests easier for physicians to submit. For a time, Cephalon imposed a quota on its sales representatives that required them to obtain completed MIRFs from physicians upon whom they called at a rate that exceeded one such request per day. Although that quota was discontinued, sales representatives continue to encourage doctors to make such requests and lead discussion about the availability of such information from Cephalon so that requests when made almost always are directed to available information that Cephalon believes will make off-label use of its products appear more attractive. Physicians are never told about the existence of information that would make off-label use of a Cephalon product less attractive. Requests to Cephalon's home office for such information from physicians are thus much more rare than requests for favorable information.

58. For example, because available literature regarding Actiq is laden with disclaimers regarding off-label use, Cephalon's management considers it more likely to discourage than to encourage off-label use. Cephalon sales representatives thus are advised not to initiate discussions with physicians about the existence or availability of such materials and certainly never invite them to request such information. As a result, such information is rarely requested from Cephalon by physicians, whereas information that Cephalon regards as favorable for off-label usage frequently is requested by

physicians upon whom Cephalon sales representatives have recently visited.

59. Another tool that Cephalon has provided its sales representatives to advance off-label sales is printouts of ICD-9-CM Diagnostic Codes related to potential off-label uses of its products. Such tools do not provide any material value to legitimate marketing efforts. Rather, they are distributed by Cephalon to sales representatives primarily so that sales representatives will coach physicians on which diagnosis codes may be used to circumvent reimbursement edits of public and private insurers that are designed to limit payment for off-label use of drugs like Cephalon's to a limited set of disease states.

60. Relator heard this coaching practiced described at district sales meetings in Cancun in February 2002, in Detroit in the fall of 2002, and in Cleveland in the fall of 2003. For example, with respect to the off-label use of Provigil, sales representatives were informed at those sales meetings that physicians could be coached to use ICD-9-CM diagnostic code for Idiopathic Hypersomnia (code 780.54, which relates to an disorder of actual sleep) to gain reimbursement for treatment of mere malaise or fatigue, which is properly identified by ICD-9-CM diagnostic code 780.7.

61. At the same time Cephalon was pressuring its existing sales force to market off-label so that the company could make its sales growth goals, it also developed hiring criteria for potential new sales representatives that inquired whether the candidate would be able to "work within the gray area" of off-label marketing. Cephalon has looked to hire only sales representatives that demonstrated understanding that off-label marketing, while explicitly disavowed in official statements of company policy and practice, was encouraged, expected, and necessary in the field in order for the company and the sales representative, individually, to reach the growth goals upon which Cephalon measured

"success." It has also looked to hire sales representatives who it believed could engage in extensive off-label marketing effectively -- but not too obviously.

62. Cephalon's message to its sales representatives to engage in subtle but extensive off-label marketing has been broadly understood and implemented. Predominantly because of off-label marketing efforts (including the conduct set forth above), sales of Provigil have risen from $25.3 million in 1999 to projected sales of $375 - $425 million for 2004. During the same period, off-label uses of Provigil have grown to account for at least 80-90% of all such sales.

63. Top bonuses earned by sales representatives most willing to market off-label similarly increased by approximately 100% over the top bonuses paid before expanding off-label sales became the subject of substantial financial incentives.

64. Approximately 8.5% of all Provigil sales are paid for by Medicaid.

B. Cephalon Has Illegally Promoted Gabitril in the Same Manner as Provigil.

65. Since Cephalon purchased the rights to Gabitril from Abbott Laboratories in late 2000, Chephalon has illegally promoted that drug predominantly for off-label indications in an essentially identical manner to that it uses for Provigil.

66. Gabitril is a selective gamma-aminubutyric acid ("GABA") reuptake inhibitor that has been approved by the FDA only for use as adjunctive therapy in the treatment of partial seizures in epileptic patients. Cephalon however makes virtually no direct marketing effort to sell Gabitril for its FDA-approved use. Rather, Cephalon has mounted a national marketing campaign to promote Gabitril almost exclusively for unapproved uses ranging from treatment for anxiety to insomnia to neuropathic pain relief. Indeed, because Gabitril marketability for its on-label use is so limited, Cephalon sales

representatives are actually discouraged by their management from devoting marketing time to neurologist and other physicians with specialties relating to epilepsy. They are encouraged, instead, to concentrate their sales calls on psychiatrists who are known by Cephalon to prescribe subscribe substantial amounts of anti-anxiety medications and as a cheaper alternative for some of the same off-label uses for which Pfizer's Warner-Lambert division was recently fined for improperly marketing Neurontin.

67. All the violations of the law described in paragraphs 41-64, above, with respect to Provigil have occurred as well with respect to Gabitril, which is generally marketed to the same physicians at the same time as Provigil.

68. Cephalon's improper marketing of Gabitril has been very profitable. In just four years, Gabitril's annual sales revenues exploded from $4.4 million in the year Cephalon acquired rights to the drug (2000) to anticipated sales of $80 - $90 million for 2004. Approximately 90% of sales for Gabitril are for off-label uses. More than 23% of all Gabitril sales are paid for by Medicaid.

C. Cephalon Has Illegally Promoted Actiq.

69. Cephalon has aggressively promoted Actiq for off-label use in much the same manner as Provigil and Gabitril, since it purchased Anesta Corporation, the former owner of rights in that drug, in October, 2000.

70. Actiq uses Cephalon's proprietary oral transmucosal delivery system (a lollipop) to deliver fentanyl citrate, a powerful, Schedule II opioid analgesic (painkiller) to treat pain. Its sole FDA-approved use is for treating breakthrough cancer pain in opioid tolerant patients. "Breakthrough" cancer pain is a flare of moderate to severe pain that "breaks through" medication cancer patients use

to control their persistent pain. Actiq's side effects are typical of opioids, and can range from somnolence, nausea, vomiting and dizziness to respiratory depression, which can be life threatening.

71. From October, 2000 until the beginning of 2004, Cephalon marketed Actiq through a group of 60 to 90 Cephalon field sales representatives and managers who specialized in that product and who made sales calls primarily to pain specialists and oncologists. As a result of efforts by those sales representatives to expand the market to off-label pain applications in pain management, sales of Actiq increased from $15.2 million in 2000 to $237.5 million in 2003.

72. Specifically with a view toward expanding the market to off-label pain applications even further, in the beginning of 2004, Cephalon combined and expanded its sales forces so that now all of its sales representatives and managers market Actiq to a broader group of physicians that now includes internists, general practitioners, and family practitioners who might prescribe the mediation for outpatient uses. Cephalon sales representatives market off-label uses of Actiq to such physicians and coaches them with respect to ICD-9-CM diagnostic codes that can be used in support of reimbursement claims.

73. Although the general effectiveness of opioids like Actiq in treating various forms of pain is well known, the self-dosing nature of Actiq's delivery system together with the high risks associated with overdosing on opioids raise safety concerns as the primary danger raised by off-label – and/or inadequately supervised – use of this drug. For that reason serious concern has been expressed even within Cephalon about the risks inherent with its marketing decision to promote off-label use of Actiq to internists, general practitioners, and family practitioners who may not have the experience with opioids necessary to fully appreciate the dangers of the drug

and the need to ensure that it is not over-prescribed or prescribed without sufficient patient education.

74. Despite these concerns, and despite the lack of scientific studies or compendia discussion that support the safety and efficacy of Actiq for any of the wide variety of outpatient off-label pain treatments it promotes, Cephalon has elected to change its marketing model as of 2004 so that more sales representatives with less expertise about the drug are now marketing the product to a larger pool of physicians (also with less expertise in pain management and opioids) in an effort to further accelerate the growth of off-label use of the product.

75. Primarily as a result of its off-label marketing efforts, Cephalon's projects total sales of Actiq in 2004 will total $325 - $375 million. As of 2004, over 90% of Actiq sales are for off-label uses. Approximately 8.3% of all Actiq sales are paid for by Medicaid.

Count I
Federal False Claims Act
31 U.S.C. §§3729(a)(1) and (a)(2)

76. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

77. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

78. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

79. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

80. Each prescription that was written as a result of defendant's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label or illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

81. Relator cannot at this time identify all of the false claims for payment that were caused by Cephalon's conduct. The false claims were presented by thousands of separate entities, across the United States, and over many years. Relator has no control over or dealings with such entities and has no access to the records in their possession.

82. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

83. By reason of the defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid many thousands of claims, amounting to many hundreds of millions of dollars, for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by Cephalon.

Count II
California False Claims Act
Cal Govt Code §12651(a)(1) and (2)

84. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

85. This is a claim for treble damages and penalties under the California False Claims Act.

86. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

87. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

88. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

89. By reason of the defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

90. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count III
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1) and (2)

91. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

92. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

93. By virtue of the acts described above, defendant knowingly presented or caused to be

presented, false or fraudulent claims to the Delaware State Government for payment or approval.

94. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

95. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

96. By reason of the defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

97. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count IV
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

98. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

99. This is a claim for treble damages and penalties under the Florida False Claims Act.

100. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

101. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be

made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

102. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

103. By reason of the defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

104. The State of Florida is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count V
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

105. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

106. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

107. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

108. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

109. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

110. By reason of the defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

111. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count VI
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(1), (2)

112. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

113. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

114. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

115. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

116. The Illinois State Government, unaware of the falsity of the records, statements and

claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

117. By reason of the defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

118. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count VII
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1), (2)

119. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

120. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

121. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

122. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

123. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and

continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

124. By reason of the defendant's acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

125. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count VIII
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a), (b)

126. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

127. This is a claim for treble damages and penalties under the Nevada False Claims Act.

128. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

129. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

130. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

131. By reason of the defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

132. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count IX
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-2F-1 et seq.

133. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

134. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

135. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

136. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

137. The New Mexico Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

138. By reason of the defendant's acts, the State of New Mexico has been damaged, and

continues to be damaged, in substantial amount to be determined at trial.

139. Additionally, the New Mexico State Government is entitled to civil penalties for each and every violation alleged herein.

Count X
New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

140. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

141. This is a claim for treble damages and penalties under the New York False Claims Act.

142. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Governments for payment or approval.

143. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

144. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

145. By reason of the defendant's acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

146. Additionally, the New York State Government is entitled to civil penalties for each and every violation alleged herein.

Count XI
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §71-5-182(a)(1)

147. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

148. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

149. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

150. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

151. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

152. By reason of the defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

153. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count XII
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

154. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

155. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

156. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

157. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

158. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

159. By reason of the defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

160. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count XIII
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1), (2)

161. Relator realleges and incorporate by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

162. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

163. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

164. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

165. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

166. By reason of the defendant's acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

167. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count XIV
District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §1-1188.14(a)(1), (2)

168. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

169. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

170. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or 2approval.

171. By virtue of the acts described above, Cephalon knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

172. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Cephalon's illegal off-label marketing practices and illegal inducements.

173. By reason of the defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

174. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Cephalon.

Count XV
Unlawful Retaliation
31 U.S.C. §3730(h)

175. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 75 of this Complaint.

176. This is a claim for damages resulting from discrimination imposed on relator by his former employer Cephalon as a result of lawful acts done by relator in furtherance on an action under the federal False Claims Act.

177. During the course of his employment at Cephalon, relator reported the wrongdoing that he was observing to the United States and lawfully cooperated with the investigative efforts of the United States into those claims.

178. During the course of that investigation, Cephalon learned of relator's cooperation with the United States in the investigation of possible False Claims Act violations and fired relator as a result of that discovery and relator's refusal to participate as Cephalon demanded in unlawful off-label marketing Cephalon products. Prior to taking such steps in resistence to Cepahlon's unlawful behavior and demands, relator enjoyed substantial success at Cephalon and was an employee in good standing.

179. Subsequent to firing relator, Cephalon continued to discriminate against Relator by tortiously interfering with his ability to secure substitute employment through unfavorable job references. Such damaging references were not otherwise justified and were intended only to punish relator for exposing and otherwise challenging Cephalon's violations of the False Claims Act and related federal laws. Had he not reported Cephalon's misconduct to the federal government and lawfully cooperated

with their investigation, relator would not have been discriminated by Cephalon in similar fashion either before or after his forced departure from the company.

180. Since expiration of his severance benefits with Cephalon in December, 2003, relator has suffered substantial financial harm as a result of Cephalon's continuation of the pattern of discrimination against relator that commenced with Cephalon's discovery of his cooperation with federal investigators.

181. Relator therefor seeks recovery for damages he has suffered since December, 2003 as a result of such continuation by Cephalon of the unlawful discrimination against him that was initiated upon the company's discovering his cooperation with federal investigators.

Prayer

WHEREFORE, qui tam plaintiff prays for judgment against the defendant as follows:

1. that defendant cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the States and the District of Columbia's statutes set forth above;

2. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of defendant's actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of California has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Cal. Govt Code §12651(a);

4. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendant's actions, plus

a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

5. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Florida has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. §68.082(2);

6. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

7. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

8. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

9. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1)(a), (b);

10. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendant's actions, plus civil penalties for each violation of N.M. Stat. Ann. § 27-2F-4.

11. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New York has sustained because of defendant's actions, plus

civil penalties of $12,000 for each violation of N.Y. State Fin. § 189.

12. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §71-5-182(a)(1);

13. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Texas has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

14. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a)(1), (2);

15. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §1-1188.14(a)(1), (2);

16. that qui tam plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the States and the District of Columbia statutes set forth above;

17. that this Court enter judgment against defendant and for qui tam plaintiff in an amount equal to two times the damages qui tam plaintiff has suffered as a result of defendant's discrimination against him;

18. that qui tam plaintiff be awarded all costs of this action, including attorneys' fees and expenses; and

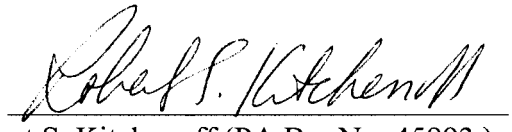
19. that all plaintiffs recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, qui tam plaintiff hereby demands a trial by jury.

Dated: December 18, 2007

WEINSTEIN, KITCHENOFF
& ASHER, LLC

By: 

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